April 24, 2013

RESPONSE TO QUESTIONS FOR THE RECORD
HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
HEARING ON
HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS
MARCH 20, 2013

RESPONSE SUBMITTED BY
JACQUELINE MITUS, MD
MCKESSON CORPORATION

Question from Representative Michael Burgess:

The Health Information Management Systems Society recommends that FDA not define "medical device" to cover software or hardware that provides clinical decision support, EHRs, simply transmits or allows other parties to read information originally sent from a medical device, or technologies that are widely used in other industries. These seem like a strong request that FDA not use mission creep to go into areas for which it has little expertise and little ability to properly review.

a. How would FDA use a clinical trial system for clinical decision support?

Response:

We concur that medical devices, currently regulated by the FDA, are fundamentally different and distinct from clinical decision support in two important ways.

First, the safety of a medical device is almost entirely dependent upon how it is manufactured. The safety of health IT on the other hand hinges upon how it is developed and, perhaps more importantly, on how it is deployed. Thus, health IT safety cannot be ensured simply through good manufacturing practices.

Second, medical devices, unlike health IT, are directly involved in the treatment of a patient, with little if any opportunity for a clinician to intervene. The majority of medical software does not directly or independently act upon a patient, but rather provides data and guidance. The ability of a "learned intermediary" to utilize professional judgment distinguishes this technology from traditional medical devices.

Consequently, clinical decision support, and health IT more broadly, is distinct from medical devices. The traditional paradigm of FDA regulation of medical devices is therefore not well suited to health IT, and a risk-based regulatory system similar to that advocated by the Bipartisan Policy Center is more appropriate.

In the context of the oversight of health IT, clinical decision support systems refer to software applications which gather, present, and, to varying degrees, interpret and act upon information to assist clinicians in the diagnosis and treatment of patients. This is very different from more administrative software such as clinical trial software which may provide registries of clinical trials or which may manage eligibility and/or registration into trials.

In some instances, physicians may utilize a clinical decision support system in the care of a patient who is participating in a clinical trial. It also is foreseeable that a clinical decision support system may utilize information obtained as a result of clinical trials, such as drug interactions or treatment recommendations associated with a medical device or pharmaceutical compound. However, it is difficult to envision a situation where the FDA would use a clinical trial system for clinical decision support in the context of the health IT discussion.